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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,887	08/13/2001	Unterschrift des Erfinders	WEH205	5443

7590

06/10/2005

Horst M Kasper
13 Forest Drive
Warren, NJ 07059

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,887

Applicant(s)

ERFINDERS ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004 and 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Amendment filed 10/29/04 and Response to Notice of Non-Compliant Amendment filed 3/28/05 have been entered. New claim 32 has been added. All pending claims, which are claims 1-32, are being considered for further examination on the merits.

Claim Objections

2. Claims 1-17 and 22-31 are objected to because of the following informalities:
 - a) Each of claims 1-16 and 22-26, line 1, "prothesis" must be changed to --prosthesis--.
 - b) Claim 17, line 1, "cardiovascular prothesis" should be changed to --a cardiovascular prosthesis--.
 - c) Each of claims 27-31, "cardiovascular prothesis" should be changed to --a cardiovascular prosthesis--.
 - d) Claim 6, line 10, "have" should be changed to --has-- and "reservoirs" should be changed to --reservoir--.
 - e) Claim 7, line 11, "have" should be changed to --has--.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 12 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 12 recites the limitation "the medium reservoirs" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that "the medium reservoirs are comprised of expandable blood bags" should be changed to --the medium reservoir is comprised of an expandable blood bag--.

5. Claim 30 is indefinite because it is unclear how endothelial cells have a pumping capacity.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Dunkelman et al. (WO 97/49799 as cited in applicant's IDS).

Dunkelman et al. discloses a method for covering and cardiovascular prosthesis with endothelial cells with all the elements of claims 17-21 and 27-32. See Figure 4, page 3, lines 7-14, pages 7-8, lines 3-29 and page 11, lines 1-12 and pages 11-12, lines 28-3. The method includes apparatus comprising a chamber (46), pumping tube (58), adapters (33), cardiovascular prosthesis (26), reservoir (10), and pumping device (50). Because all of the method steps are

met by Dunkelman et al., all of the structural limitations of the product claims of 1-16 and 22-26 are also met. A cardiovascular prosthesis has an initial sub-confluent seeding of endothelial cells on the surface thereof and then forms a confluent monolayer of endothelial cells.

Response to Arguments

8. Applicant's arguments filed 10/29/04 have been fully considered but they are not persuasive. Applicant argues that the shearing forces indicated in the Dunkelman et al. reference only have a small value that cannot influence growth of the cells, and that no growth of cells occurs under shearing stress. The examiner disagrees. Shear and/or radial stresses are added to the vascular graft of Dunkelman et al. during seeding and culturing, which means that the cells do indeed grow (i.e. culture) under the shearing stress. See page 10, lines 8-9 and page 11, lines 29-31. Dunkelman et al. discloses that cells which are seeded and cultured in a dynamic environment are more likely to tolerate the physical conditions which exist in the human body once implanted than cells that are seeded and cultured in a static environment. This indicates that the shearing forces are indeed influencing growth of the cells. See page 2, lines 14-17 and page 3, lines 9-12. Additionally, the shearing and radial stresses simulate physical conditions, which indicates that their forces will reflect physiological values. See page 10, lines 8-9.

9. Applicant refers to claim 1 of Dunkelman et al. as reading "...to cause the cells to become confluent and flatten...". The examiner is confused because claim 1 of the reference reads: "An apparatus, comprising: a chamber having a first port and a second port for flow of fluid therethrough; a means for connecting at least one vascular graft within said chamber; and a means for imparting radial and shear stresses to said at least one vascular graft." The limitation

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cited by applicant is not claimed in claim 1. See Exhibit A, attached hereto. The examiner is also confused about applicant's reference to page 8 of Dunkelman et al. as disclosing a multiple-step procedure involving four aliquots, overnight incubation being dispensable for production of a confluent monolayer (paragraph 4), the shear stress being entered only at a lower value and therewith a non-physiological value, and a confluent, not completely stable endothelial cell monolayer being obtained since partial cell disengagements occur (paragraph 3). As shown in Exhibit B, attached hereto, there is no mention of any of these points referenced by the applicant.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

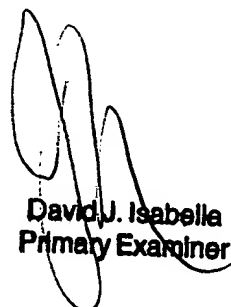
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner